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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/605,783	06/27/2000	Jiangchun Xu	210121.427C16	4968

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EXAMINER	
JOHANNSEN, DIANA B	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 09/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/605,783	XU ET AL.	
	Examiner	Art Unit	
	Diana B. Johannsen	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35,36 and 62-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35,36 and 62-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 June 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *0103; 0704*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to the Terminal Disclaimer filed January 29, 2003, the Reply filed July 30, 2003, and the complying complete set of claims filed December 1, 2003. Claims 35, 62-63, and 65 have been amended, and claims 1-34 and 37-61 have been canceled. Claims 35-36 and 62-65 are now pending and under consideration.

This action is NON-FINAL.

Response to the Remarks of June 30, 2003 (regarding SEQ ID Nos 110 and 113)

2. Applicants' traversal of the basis of the notice of non-responsive amendment of January 29, 2003 is noted. Upon further consideration, the examiner agrees that both claims reciting the polypeptide of SEQ ID NO: 113 (and fragments thereof) and claims reciting the polypeptide encoded by SEQ ID NO: 110 (and fragments thereof) would properly be encompassed by the elected Invention.

Priority

3. With regard to Applicants' specific reference to earlier filed applications, the status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Specification

4. The title of the invention is not descriptive of the subject matter of the elected invention. A new title is required that is clearly indicative of the invention to which the claims are directed.

Compliance with Sequence Rules

5. The specification contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a) and (a)(2). However, the specification fails to comply with one or more of the requirements of 37 CFR 1.821 through 1.825 because the specification recites sequences that lack description by the appropriate sequence identifier set forth in the "Sequence Listing" as required by 37 CFR 1.821(d). See, for example, Figures 8-9. Appropriate corrections for compliance are required. Specifically, Applicant must either file substitute Figures that recite the appropriate sequence identifiers, or amend the brief description of the figures so as to set forth said sequence identifiers. See MPEP 2422.02.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 35-36 and 62-65 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods for stimulating and/or expanding T cells using a peptide encoded by a particular subsequence of SEQ ID NO: 110 (the peptide disclosed as SEQ ID NO: 337), and for isolated T cell populations

comprising T cells prepared by such methods, does not reasonably provide enablement for methods for stimulating and/or expanding T cells using the numerous other polypeptides encompassed by the claims, or for isolated T cell populations comprising T cells prepared by such methods. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: (A) the breadth of the claims; (B) the nature of the invention; (C) the state of the prior art; (D) the level of one of ordinary skill; (E) the level of predictability in the art; (F) the amount of direction provided by the inventor; (G) the existence of working examples; and (H) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (*MPEP* 2164.01(a)).

The claims as written encompass methods "for stimulating and/or expanding T cells" using "a polypeptide comprising at least a 9 amino acid fragment of the amino acid sequence encoded by SEQ ID NO: 110," as well as isolated T cells prepared by the claimed methods. It is noted that SEQ ID NO: 110 and the predicted amino acid sequence encoded thereby, SEQ ID NO: 113, were first disclosed in parent application 09/020,956, filed February 9, 1998. It is further noted that while the specification states that SEQ ID NO: 110 is expressed in both prostate tumor tissue and normal prostate

tissue (see, e.g., pages 129-130 and 177), the specification provides evidence that detection of SEQ ID NO: 110 expression in cells obtained from patient blood samples would be one factor that one of skill in the art would reasonably consider in diagnosing prostate cancer, as such expression was evident in 6 of 8 samples from prostate cancer patients, and absent in 4 of 4 samples from normal blood samples (see pages 189-190 of the specification).

It is unpredictable as to whether one of skill in the art could make and use the invention in a manner reasonably commensurate with the claims. The specification exemplifies only a single peptide contained within SEQ ID NO: 113 (and encoded by SEQ ID NO: 110) that stimulates T cells (see the discussion of SEQ ID NO: 337 at pages 144-145 of the specification). In contrast, the claims as written encompass the use of thousands of different peptides and polypeptides in stimulation/expansion of T cells, the large majority of which are structurally unrelated to SEQ ID NO: 337. The specification discloses that a database search for sequences homologous to the polypeptide encoded by SEQ ID NO: 110 did not reveal any significant homologies (page 125); accordingly, the specification does not provide evidence, e.g., that SEQ ID NO: 110 or any polypeptide encoded thereby is homologous to a prior art molecule that is known to encode or contain epitopes that stimulate T cells. Thus, given the teachings of the specification, it is unknown as to whether any molecules encompassed by the claims (other than SEQ ID NO: 337) actually have the functional property of stimulating T cells. Lacking guidance from the specification, one of skill in the art may look to the teachings of the art for further direction and enablement of a claimed invention. In the

instant case, the prior art reference of Billing-Medel et al (U.S. Patent No. 6,130,043) does disclose a prostate-specific polypeptide sharing regions of identity with instant SEQ ID NO: 113 for which basis is provided in Billing-Medel et al's priority application 08/850,713. However, Billing-Medel et al provide no evidence that this region or portions thereof have the ability to stimulate T cells; accordingly, the Billing-Medel et al reference does not support the enablement of the invention of the instant claims. Further, the prior art reference of Bixler et al (U.S. Patent No. 5,785,973 [7/1998; filed 6/1995]) teaches that while some general characteristics of T cell determinants are known (e.g., typical lengths), there are conflicting theories in the art with regard to what features or properties cause a particular peptide to actually function as a T cell determinant (see the section entitled "T-Cell Determinants" at columns 5-7, and particularly the conclusion at column 7, lines 36-37 that "A clear picture of what factors are important to the prediction of a T-cell determinant is yet to emerge"). Thus, the teachings of the prior art indicate that only certain, particular polypeptide fragments function as T cell determinants, and further that the guidance provided in the art at the time the instant invention was made was not sufficient to allow one of skill to predict which peptides encompassed by the instant claims -- if any --other than SEQ ID NO: 337 will actually stimulate T cells. While one of skill in the art could conduct further experimentation aimed at determining which of the thousands of molecules encompassed by the claims function as T cell determinants, the outcome of such experimentation cannot be predicted, and it is therefore unknown as to whether any molecules other than SEQ ID NO: 337 could actually perform this function. Accordingly,

given the lack of guidance in the specification and in the art, and the unpredictability of the art, it would require undue experimentation to make and use Applicants' invention in a manner reasonably commensurate in scope with the instant claims.

8. Claims 35-36 and 62-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 35-36 and 62-65 are indefinite over the recitation of the limitation "the amino acid sequence encoded by SEQ ID NO: 110" in claims 35 and 63. The polynucleotide sequence set forth in SEQ ID NO: 110 may clearly encode multiple different amino acid sequences, and it is not clear which of these would constitute "the" amino acid sequence encoded by SEQ ID NO: 110. Further, it is noted that there is insufficient antecedent basis in the claims for a single, particular "amino acid sequence encoded by SEQ ID NO: 110." Clarification is required.

Claims 35-36 and 62-65 are indefinite over the recitation of the limitation "capable of stimulating a human T-cell response" in claims 35, 62-63, and 65. Capability is a latent characteristic, and any amino acid sequence may be "capable of stimulating a human T-cell response" if sufficiently modified and properly presented. It is not clear how one might differentiate an amino acid sequence that is "capable of stimulating a human T-cell response" from any other amino acid sequence. Accordingly, the claims are vague and indefinite.

Claims 35-36 and 62 are indefinite because it is unclear whether the claims are drawn to a method for "stimulating and/or expanding" a population of T cells that is

"specific for a prostate-specific protein," or whether the claims are drawn to a method in which naïve T cells are first activated (so as to become "specific for" a particular prostate-specific protein encoded by SEQ ID NO: 110), and then stimulated and/or expanded. The language of the claim preamble is ambiguous: the recitation "method for stimulating and/or expanding T cells specific for a prostate-specific protein" could refer to either of the above possible methods. Further, while the single method step of "contacting" appears to be sufficient only to stimulate and/or expand previously activated T cells (as the claim merely requires contacting with a polypeptide...under conditions and for a time sufficient to permit the stimulation and/or expansion of T cells), the claims recite only the use in this method step of "T cells" (rather than, e.g., "T cells specific for a prostate-specific protein"). Accordingly, it is unclear as to what is required to meet the requirements of the claims, and it further appears that the step recited in the claim may be insufficient to meet this objective. Clarification is required.

Claims 62 and 65 are indefinite over the recitation of the language "amino acid residues encoded by...." in the claims. It is unclear whether the claims are actually intended to encompass the selection of any of the recited residues, or whether Applicant intends to limit the claims to particular fragments encoded by SEQ ID NO: 110. This rejection could be overcome by amending the claims so as to replace the recitations of "amino acid residues encoded by" with the language "the amino acid sequence encoded by," so as to clearly limit the claims to particular, contiguous sequences encoded by SEQ ID NO: 110.

Terminal Disclaimer

9. The terminal disclaimer filed on January 29, 2003 disclaiming the terminal portion of any patent granted on this application that would extend beyond the expiration date of U.S. Patent No. 6,261,562 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Drawings

10. The drawings are objected to because they include text that is insufficiently large and/or dark to be fully legible (Figures 2, 3, and 6-12) and because of inadequate margins (Figures 6, 8-10, and 12). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the

examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 571/272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Diana B. Johannsen
Primary Examiner
September 16, 2004